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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,798	10/18/2005	Satoshi Yoshida	07580.0008	6122
22852	7590	07/28/2009		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER CHEN, CATHERYNE	
			ART UNIT	PAPER NUMBER
			1655	
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			07/28/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/553,798

**Applicant(s)**

YOSHIDA ET AL.

**Examiner**

CATHERYNE CHEN

**Art Unit**

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2 and 3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

### **DETAILED ACTION**

The Amendments filed on Sept. 13, 2007 has been received and entered.

Currently, Claims 2-3 are pending. Claims 2-3 are examined on the merits.

### ***Response to Arguments***

Applicant's arguments, filed Oct. 15, 2007, with respect to the rejection(s) of Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamanouchi (JP 2000281584 A with translation provided) and Netdoctor ([www.netdoctor.co.uk/ate/heartandblood/202771.html](http://www.netdoctor.co.uk/ate/heartandblood/202771.html)) and Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamanouchi (JP 2000281584 A with translation provided) and Kojima et al. (1991, Blood, vol. 77, pages 937-941) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the following.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamanouchi (JP 2000281584 A with translation provided) in view of Levine et al. (1989, Int Conf AIDS, 5, 406), Nissen et al. (1988, Blood, 72, 2045-2047) and Weisbart et al. (1985, Nature, 314, 361-363).

Yamanouchi teaches neutrophil activator consists of pumpkin seed is also known as *Cucurbita moschata* (see <http://www.tropilab.com/cucur-max.html>), safflower is also known as *Carthamus tinctorius* (see [http://www.uni-graz.at/~katzer/engl/Cart\\_tin.html](http://www.uni-graz.at/~katzer/engl/Cart_tin.html)), plantago (*Plantago asiatica*), and *Lonicera japonica* (Abstract). 5.0 g or 41.67% of Japanese pumpkin seed, 3.0 g or 25% of safflower, 1.0 g or 8.33% of psyllium is also known as *Plantago asiatica* (see <http://www.herbalremedies.com/psylliumhusk.html>), 3.0 g or 25% of Japanese honeysuckle is also known as *Lonicera japonica* (see <http://plants.usda.gov/java/profile?symbol=LOJA>). The gram weights can be expressed as percentage by dividing the weight of each plant by the total amount. However it does not teach a method of treating neutropenia.

Levine et al. teaches use of GM-CSF for patients with neutropenia (Abstract).

Weisbart et al. teaches GM-CSF is a neutrophil-activating factor (Abstract, last sentence).

Cucurbita moschata, Carthmus tinctorius, Plantago asiatica, and Lonicera japonica are neutrophil activators. Neutrophil activators, exemplified by GM-CSF, can be used to treat patients with neutropenia. Thus, an artisan of ordinary skill would reasonably expect that the composition of Yamanouchi could be used to treat neutropenia because neutrophil activator is used to treat neutropenia. This reasonable expectation of success would motivate the artisan to use the claimed ingredients in the reference composition to treat neutropenia. Thus, using the claimed ingredients in the reference composition to treat neutropenia is considered an obvious modification of the references.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamanouchi (JP 2000281584 A with translation provided) in view of Kojima et al. (1991, Blood, 77, 937-941) and Falanga et al. (1999, Blood, 93, 2506-2514).

Yamanouchi teaches neutrophil activator consists of pumpkin seed is also known as Cucurbita moschata (see <http://www.tropilab.com/cucur-max.html>), safflower is also known as Carthmus tinctorius (see [http://www.uni-graz.at/~katzer/engl/Cart\\_tin.html](http://www.uni-graz.at/~katzer/engl/Cart_tin.html)), plantago (Plantago asiatica), and Lonicera japonica (Abstract). 5.0 g or 41.67% of Japanese pumpkin seed, 3.0 g or 25% of safflower, 1.0 g or 8.33% of psyllium is also known as Plantago asiatica (see <http://www.herbalremedies.com/psylliumhusk.html>), 3.0 g or 25% of Japanese honeysuckle is also known as Lonicera japonica (see

<http://plants.usda.gov/java/profile?symbol=LOJA>). The gram weights can be expressed as percentage by dividing the weight of each plant by the total amount. However it does not teach a method of treating aplastic anemia.

Kojima et al. teaches the increase of neutrophil count is effective as treatment of aplastic anemia by administrating G-CSF in patients (Introduction).

Falanga et al. teaches G-CSF has neutrophil activating effect (page 2506, Introduction, left column, paragraph 2).

Cucurbita moschata, Carthmus tinctorius, Plantago asiatica, and Lonicera japonica are neutrophil activators. Neutrophil activators, exemplified by G-CSF, can be used to treat patients with aplastic anemia. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use ingredients that can activate neutrophils because neutrophil activators can be used to treat aplastic anemia. One would have been motivated to use the composition for the expected benefit of treating aplastic anemia. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

### **Conclusion**

No claim is allowed.

### **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael V. Meller/  
Primary Examiner, Art Unit 1655